REMARKS

Introduction

This communication is supplemental to the amendment filed April 7, 2003, which was responsive to a final office action dated November 5, 2002, concerning the above-referenced patent application. While no other fees are believed due, the PTO is authorized to invoice account No. 190741 for any charges deemed necessary.

Applicant notes that the examiner has not initialed and returned a copy of PTO form 1449. Therefore, as a matter of courtesy, applicant submits herewith another PTO 1449 form, along with the references cited in the IDS. Applicant respectfully requests that the examiner initial the document.

Status of the Claims

In this amendment, applicant added new claim 47. Support for claim 47 can be found on page 5, lines 17-31, and in example 2 of the instant specification. Upon entry of this amendment, claims 1-10, 16, and 18-47 will be pending.

35 U.S.C. § 112, 1st paragraph

To support the examiner's contention of non-enablement, the examiner cited the Federal Circuit's opinion in *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200 (Fed. Cir. 1991). In particular, the examiner maintained that the facts of the present case are similar to *Amgen* since "the possible [number of null IGF-I] variants are 70 to the 20 power" and that null IGFs do not represent a narrow subset of IGF analogs (advisory action at 2). The examiner arrived at this notion by pointing to the application and asserting that "the specification defines null IGF as 'IGF-I which has amino acid sequence alterations at one or more sites in the molecule'" (advisory action at 2).

However, the examiner only quoted part of the null IGF definition provided in the specification. The examiner failed to indicate that the specification also recites that a "[n]ull IGF-I retains its ability to bind IGFBP-3, but is altered in its receptor binding and/or activating properties" (specification at 5, lines 17-20). Also, the specification specifically teaches preferred null IGF analogs and provides references where guidance on such analogs

can be found. As such, the genus of null IGFs in the present invention is hardly "70 to the 20^{th} power."

In addition, applicant's claims are directed to specific null IGF analogs, with defined amino acid substitutions. *See*, for example, claims 18-44. Therefore, given the level of guidance in the art on these specific null IGF analogs, the *in vivo* working examples described in the specification, and a declaration attesting to the therapeutic value of these analogs, applicant has more than adequately disclosed how to make and use a null IGF for treatment of cancer.

Finally, with regard to the examiner's recitation of the MPEP, and statement that "where an explicit definition is provided by the applicant for a term, that definition will control" (advisory action at 2), applicant respectfully contends that the definition of null IGF as provided in the specification is not inconsistent with its ordinary meaning. Although an inventor is permitted to be her own lexicographer and choose to redefine a term, there is no indication in the instant case that the applicant is providing a new definition for null IGF. The definition provided in the specification is consistent with its ordinary meaning. Therefore, applicant has not broadened the meaning of "null IGF" beyond that which is consistent with its ordinary meaning.

CONCLUSION

Applicant submits that this application is in condition for allowance and solicits an early indication to that effect. Should the Examiner believe that further discussion of any remaining issues would advance the prosecution, a telephone call to the undersigned is courteously invited.

Respectfully submitted,

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